Remarks

Claims 19-43 are pending in the subject application. Applicants acknowledge that claims 19, 22-29, and 33-43 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 20 and 21, canceled claims 19, 22-29, and 33-43, and added new claims 44-45. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, paragraph 257 and the previously presented claims). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 20, 21, 30-32, and 44-45 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, the Examiner states that the Information Disclosure Statement (IDS) "filed 12/30/02 fails to comply with 37 C.F.R. § 1.98(a)(2)." Specifically, the Examiner indicates that the foreign patent documents (cited as F1-F3) and the non-patent literature publications (cited as R1-R42, R45, R46 and R46-R84) were not considered because a copy of the references were not found in the subject application. Applicants note that the non-patent references cited as R43, R44, R47, and R85-97 have been considered and made of record. Because the return receipt postcard (copy enclosed) evidences receipt by the Patent Office of the IDS filed December 30, 2002 and the listed references, Applicants believe that no fees are due in connection with having the references considered and made of record. For the Examiner's convenience, Applicants have provided a clean copy of Form PTO/SB/08 filed December 30, 2002 along with the references that appear to have been misplaced by the Patent Office and respectfully request that the remaining references be considered and made of record by the Examiner in the subject application by initialing and returning the form.

Claims 20 and 21 are objected to because of informalities. Specifically, the claims are objected to for using the abbreviations "DAO" and "DDO." In accordance with the Examiner's request, claim 20 has been amended to recite "D-amino acid oxidase" with the abbreviation "DAO" in parentheses. The issue with respect to "DDO" is considered moot in view of its cancellation as being drawn to a non-elected invention. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 20, 21, and 30-32 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants assert that the claims are definite. Applicants have amended claim 20 to indicate that the polypeptide fragment has DAO enzymatic activity and the issue as relates to claim 22 has been rendered moot in view of the amendment made to the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 20 and 30-32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention and as non-enabled by the subject specification. The Office Action argues that the as-filed specification fails to provide adequate written description for the genus of DAO polypeptides because the specification teaches the structure of "only a few representative species of such DAO and DDO polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having DAO or DDO activity." The Office Action concludes that because of the lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. Applicants traverse.

Applicants respectfully submit that these rejections have been improperly applied against the claimed invention as the scope of the claimed invention was limited to SEQ ID NO: 7 by way of the Patent Office Restriction Requirement of October 4, 2004. In this Restriction Requirement, Applicants were required to elect a single polypeptide or polynucleotide sequence for examination on the merits (*e.g.*, the DAO and DDO sequences identified in the claims as SEQ ID NOs: 7-10 and 21-22, respectively) with respect to the claimed methods (see Restriction Requirement of October 4, 2005, pages 2 and 3). In Applicants' response, the DAO polypeptide of SEQ ID NO: 7 was elected for examination and there has been no indication that the previous Restriction Requirement has been rescinded by the Patent Office. Thus, it is respectfully submitted that the Patent Office has considered the currently pending methods, as they relate to the use of DAO or DDO polypeptides, to be patentably distinct with the human DAO sequence of SEQ ID NO: 7 elected for examination on the merits and the human DDO sequence identified in SEQ ID NOs: 21 and 22 standing non-elected.

Accordingly, the use of DDO polypeptides in the claimed methods stands withdrawn from consideration and should not be subject to rejection. Applicants have removed the language directed to the non-elected subject matter and amended the currently pending claims to comport with the Restriction Requirement promulgated by the Examiner (namely, the insertion of the elected sequence within the pending claim set). Accordingly, Applicants respectfully request that the rejections be reconsidered and withdrawn.

As indicated in the preceding paragraph, Applicants submit that the enablement and written descriptioin rejection has been improperly applied to the claimed invention in view of the Restriction Requirement of October 4, 2004 and should be withdrawn. However, Applicants also respectfully submit that the as-filed specification provides adequate written description for the genus of DAO polypeptides recited by the claims. As the Patent Office is aware, the claims in question are directed to methods of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder that comprise contacting mammalian DAO with candidate compounds. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention and that the claims are enabled by the subject specification. For example, mammalian DAO polypeptides (including human, chimpanzee, cow, mouse, rat, guinea pig, pig, rabbit, and hamster DAO sequences) were known and disclosed in public databases and prior art publications prior to the filing date of the instant invention. As such, Applicants respectfully submit that the skilled artisan would have recognized that the inventors were in possession of the claimed methods of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder that comprise contacting mammalian DAO with candidate compounds and that the inventors were in possession of a representative number of species of DAO polypeptides.

Applicants further submit that the subject claims are factually distinct from the legal decision, related to written description, that appears to form the basis of the instant rejection. It appears that the rejection is predicated upon *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) where the court held that the patent in question failed to disclose a representative number of recombinant insulin molecules to convey possession of the genus of all recombinant mammalian insulin molecules. The subject invention is directed to

methods of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder that comprise or contacting a mammalian D-amino acid oxidase (DAO) polypeptide or a fragment thereof that has DAO enzymatic activity with a test compound; and determining whether said compound (i) selectively reduces the enzymatic activity of said polypeptide; or (ii) selectively binds said polypeptide. The subject invention is not directed to novel, previously unknown polypeptides or nucleic acid molecules, rather it is directed to methods of screening known mammalian DAO polypeptides for their ability to interact with candidate molecules. Accordingly, reconsideration and withdrawal of the written description rejection set forth under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 20 and 30-32 are also rejected under 35 U.S.C. § 112, first paragraph being non-enabled by the subject specification. The Office Action argues that the claimed invention is not enabled by the subject specification on the basis that there is no evidence in the specification that link other "biological activities" of DAO, such as immunological or binding activity with schizophrenia, depression, or bipolar disorder and without a clear indication of how these activities are related to the disorders. The Office Action also argues that the scope of DAO enzymes encompassed by the claims is clearly not commensurate with the scope of the claimed invention on the basis that DAO molecules produced by non-mammalian organisms differ substantially in structure from human DAO (as exemplified by SEQ ID NO: 7) and that one skilled in the art would not expect that any DAO could be used in the claimed method as inhibitors of structurally distinct DAOs would be unlikely to inhibit mammalian DAO molecules and not useful for the treatment of schizophrenia, depression, or bipolar disorder. The Office Action also argues that the specification fails to enable an invention directed to DDO (D-aspartate oxidase) activity as DDO and DAO have mutually exclusive substrates. Applicants traverse.

First, addressing the enablement rejection as it has been applied to the identification of compounds for the ability to bind to or modulate the activity of DDO, it is respectfully submitted that this rejection has been improperly applied. In the Restriction Requirement of October 4, 2004, Applicants were required to elect a single polypeptide or polynucleotide sequence for examination on the merits. The DAO and DDO sequences are identified in the claims as SEQ ID NOs: 7-10 and 21-22, respectively. Thus, it is respectfully submitted that the Patent Office has considered the currently

pending invention, as it relates to the use of DAO or DDO polypeptides to be patentably distinct. The human DAO sequence of SEQ ID NO: 7 was elected for examination on the merits and the human DDO sequence identified in SEQ ID NOs: 21 and 22 were not elected for examination. Accordingly, the use of DDO polypeptides in the claimed methods stands withdrawn from consideration and should not be subject to rejection. In order to align the claims with the elected invention, Applicants have removed the language directed to the non-elected subject matter and respectfully request that the rejection be reconsidered and withdrawn as applied to DDO polypeptides.

With respect to the enablement issue raised in the Office Action regarding the differences between mammalian and non-mammalian DAO molecules, Applicants respectfully submit that this issue has been rendered moot by way of amendment of the claim to recite mammalian DAO polypeptides. Again, this amendment has been made to harmonize the claims with the elected sequence, SEQ ID NO: 7, which is the human DAO sequence and should not be construed as acquiescing to the rejection of record.

Turning to the enablement issue as it relates to linking "biological activities" of DAO, such as immunological or binding activity with schizophrenia, depression, or bipolar disorder without a clear indication of how these activities are related to the disorders, Applicants respectfully submit that this rejection is improperly applied to the claims. The claims are directed to a method of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder, said method comprising: (a) contacting a mammalian D-amino acid oxidase (DAO) polypeptide or a fragment thereof that has DAO enzymatic activity with a test compound; and (b) determining whether said compound (i) selectively reduces the enzymatic activity of said polypeptide; or (ii) selectively binds said polypeptide; wherein a test compound that selectively reduces the enzymatic activity of said polypeptide or fragment thereof or selectively binds to said polypeptide or fragment thereof is identified as a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder.

Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983), and is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive. *Atlas Powder Co. v. E.I. Du Pont*

De Nemours & Co., 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984); *W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.

As noted above, the subject invention is directed to methods of identifying molecules that are candidates for treating schizophrenia, depression, or bipolar disorder and the as-filed specification clearly enables such screening assays. For example, the instant specification teaches a variety of methods for determining if a test compound selectively reduces the enzymatic activity of a mammalian DAO polypeptide or fragment thereof or selectively binds to a mammalian DAO polypeptide or fragment thereof by measuring the oxidative activity of the DAO polypeptide (or a fragment thereof) or the physical interaction of a test compound with the DAO polypeptide (or a fragment thereof; see paragraph 304, 305, 307, and 311). Thus, the subject specification provides ample teachings with respect to (a) contacting a mammalian D-amino acid oxidase (DAO) polypeptide or a fragment thereof that has DAO enzymatic activity with a test compound; and (b) determining whether said compound (i) selectively reduces the enzymatic activity of said polypeptide; or (ii) selectively binds said polypeptide; wherein a test compound that selectively reduces the enzymatic activity of said polypeptide or fragment thereof or selectively binds to said polypeptide or fragment thereof is identified as a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder and fully enables the claimed invention, directed to methods of identifying candidate compounds for the treatment of schizophrenia, depression, or bipolar disorder. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 21 is rejected under 35 U.S.C. § 103(a) as obvious over Prendergast *et al.* (U.S. Published Application No. 2004/0053989) in view of Swiss-Prot Accession No. P14920. The Office Action asserts that Prendergast *et al.* teach that inhibitors of D-amino oxidase (DAO) are useful for the treatment of neurodegenerative diseases, such as Alzheimer's disease (pointing to paragraph 212). The Office Action admits that Prendergast *et al.* fail to teach an assay for DAO inhibitors. Swiss-Prot Accession No. P14920 has been cited for its teaching of the human DAO polypeptide sequence. The Office Action then argues that it would have been obvious to one of ordinary skill in

the art to test compounds for their ability to inhibit the enzymatic activity of human DAO by comparing the activity of the enzyme in the presence and absence of the compound. Applicants respectfully traverse.

As the Patent Office is aware, each and every limitation of the claimed invention must be taught or suggested by the prior art in order to establish a *prima facie* case of obviousness for a particular invention (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974)). Applicants respectfully submit that the rejection of claim 21 over the teachings of Prendergast *et al.* is improper as the combination of references fails to teach the limitations recited within the presently claimed invention and that, thus, a *prima facie* case of obviousness has not been established by the combination of references. Indeed, as the Office Action admits, Prendergast *et al.* fail to teach an assay for identifying inhibitors of DAO; thus, the reference is devoid of any teaching of the recited method steps and the teachings of the Swiss-Prot polypeptide sequence does nothing to remedy this defect in Prendergast *et al.* Further, Applicants submit that the cited reference fails to suggest such an assay or that one be undertaken to identify DAO antagonists and Applicants respectfully submit that one skilled in the art would not have been motivated to undertake such a screening assay in view of the teachings of the reference. Accordingly, it is respectfully submitted that the cited combination of references fails to raise a *prima facie* case of obviousness for the claimed invention and withdrawal of the rejection is respectfully requested.

Applicants also respectfully submit that the rejection is also the result of improper hindsight reconstruction of the claimed invention. While Applicant recognizes that such a reconstruction of the invention is proper so long as an obviousness rejection takes into account only the knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure (*In re McLaughlin*, 443 F.2d 1392, 1395, 170 U.S.P.Q. 209, 212 (C.C.P.A. 1971)), it is respectfully submitted that Applicant's disclosure has been used to serve as the basis of the rejection currently of record.

Further, combining prior art references without evidence of a suggestion, teaching, or motivation simply takes the inventors' disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint

drawn by the inventor, but in the state of the art that existed at the time."). Additionally, the Court of Customs and Patent Appeals has stated, "[i]n determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972). In the case of the presently claimed invention, it is submitted that there is no motivation for one of ordinary skill in the art to apply the cited teachings without the guidance and disclosure of the presently claimed invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 30 and 32 are rejected under 35 U.S.C. § 103(a) as obvious over Prendergast *et al.* in view of Swiss-Prot Accession No. P14920 as applied to claim 21, and further in view of Ricci *et al.* (1983). The Office Action asserts that Prendergast *et al.* teach that inhibitors of D-amino oxidase (DAO) are useful for the treatment of neurodegenerative diseases, such as Alzheimer's disease (pointing to paragraph 212). The Office Action admits that Prendergast *et al.* fail to teach an assay for DAO inhibitors. Swiss-Prot Accession No. P14920 is cited to teach the sequence of human DAO and Ricci *et al.* is cited to teach that aminoethylcysteine-ketamine and derivatives thereof strongly inhibit hog kidney DAO. The Office Action then argues that it would have been obvious to one of ordinary skill in the art to use compounds taught in Ricci *et al.* as test compounds in the assay methods rendered obvious by the combination of Prendergast *et al.* and Swiss-Prot Accession No. P14920, providing the sequence for human DAO. Applicants respectfully traverse.

As noted above, Applicants submit that the combination of Prendergast *et al.* and Swiss-Prot Accession No. P14920 fail to raise a *prima facie* case of obviousness for the claimed invention as Prendergast *et al.* in combination with Swiss-Prot Accession No. P14920 fail to teach the limitations recited within the presently claimed invention. Applicants further submit that the added teachings of Ricci *et al.* fail to remedy the defects previously noted in the combination of Prendergast *et al.* and that the combination of Prendergast *et al.*, Swiss-Prot Accession No. P14920 and Ricci *et al.* fail to raise a *prima facie* case of obviousness for the claimed invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 20 and 21 are rejected under 35 U.S.C. § 103(a) as obvious over Tsai *et al.* (U.S. Published Application No. 2002/0035145) in view of Wake *et al.* (2001) and Swiss-Prot Accession No. P14920 and claims 30 and 32 have been rejected over Tsai *et al.* (U.S. Published Application No. 2002/0035145) in view of Wake *et al.* (2001) and Swiss-Prot Accession No. P14920 and further in view of Ricci *et al.* The Office Action argues that Tsai *et al.* teach that agonists of the glycine site of the NDMA receptor can be used for the treatment of schizophrenia and depression. Wake *et al.* are asserted to teach that D-serine is the endogenous agonist of the glycine site of the NDMA receptor, that DAO degrades D-serine and that therefore DAO may exert modulatory action on NDMA activity by controlling the concentration of D-serine. Wake *et al.* is also asserted to teach that exogenously applied inhibitors of DAO enhance NDMA currents. Swiss-Prot Accession No. P14920 is again cited for the teaching of the human DAO sequence. The Office Action further argues that because Wake *et al.* teach that DAO inhibitors enhance NDMA currents and Tsai *et al.* teach that agonists of NDMA receptors are useful for the treatment of schizophrenia and depression, one of skill in the art would reasonably expect antagonists for human DAO to be useful for the treatment of schizophrenia and depression. The Office Action continues that it, thus, would have been obvious to one of skill in the art to test compounds for their ability to inhibit the enzymatic activity of human DAO with the expectation that compounds thus identified would be useful for the treatment of schizophrenia and depression. Applicants traverse.

Applicants note that none of the cited references teach the steps recited in the claimed method of screening compounds for their activity as DAO antagonists or the steps recited in the claimed method of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder. Thus, it is respectfully submitted that a *prima facie* case of obviousness has not been established with respect to the claimed invention as the limitations of the claims are not taught or suggested by the cited combination of references and reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further submit that the combination of references do not render the claimed inventions obvious as there is no teaching or suggestion that increased or abnormal human DAO activity is associated with the schizophrenia, depression, or bipolar disorder nor is there any teaching in the cited combination of references that decreased levels of D-serine are associated with

schizophrenia, bipolar disorder, or depression. Indeed, Wake *et al.* teach that it was unknown, at the time of the publication of the article, whether the lack of DAO affected learning and memory in DAO deficient animals (page 28, last paragraph). Applicants respectfully submit that their disclosure has been taken as a blueprint for piecing together the prior art to defeat the patentability and that the combination of the cited prior art references, without any evidence that provides a suggestion, teaching, or motivation to combine these references, fails to raise a *prima facie* case of obviousness for the claimed invention.

Turning to the rejection of claims 30 and 32 over Tsai *et al.* (U.S. Published Application No. 2002/0035145) in view of Wake *et al.* (2001) and Swiss-Prot Accession No. P14920 and further in view of Ricci *et al.*, Applicants respectfully submit that the addition of Ricci *et al.* fails to remedy the defects noted in the combination of Tsai *et al.* (U.S. Published Application No. 2002/0035145) in view of Wake *et al.* (2001) and Swiss-Prot Accession No. P14920. Again, none of the cited references teaches the steps recited in the claimed method of screening compounds for their activity as DAO antagonists or the steps recited in the claimed method of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder and Ricci *et al.* fail to remedy this defect. Accordingly, it is respectfully submitted that a *prima facie* case of obviousness has not been established and reconsideration and withdrawal of the rejection is respectfully requested.

Claims 20 and 21 have been rejected under 35 U.S.C. 103(a) as obvious over Tsai *et al.* in view of Snyder *et al.* (U.S. Published Application No. 2002/0035145) and Swiss-Prot Accession No. P14920. In addition, claims 30 and 32 are rejected under 35 U.S.C. § 103(a) as obvious Tsai *et al.* in view of Snyder *et al.* and Swiss-Prot Accession No. P14920 as applied to claims 20 and 21, and further in view of Ricci *et al.* The Office Action argues that Tsai *et al.* teach that agonists of the glycine site of the NDMA receptor can be used for the treatment of schizophrenia and depression. Snyder *et al.* has been cited for the teaching that D-serine is an endogenous agonist of the glycine site of the NDMA receptor, that DAO is the endogenous enzyme that degrades D-serine, and that mice lacking DAO possess elevated levels of D-serine. Swiss-Prot Accession No. P14920 teaches the sequence for human DAO.

Applicants again note that none of the cited references teach the steps recited in the claimed method of screening compounds for their activity as DAO antagonists or the steps recited in the

claimed method of identifying a candidate molecule for the treatment of schizophrenia, depression, or bipolar disorder. Thus, it is respectfully submitted that a *prima facie* case of obviousness has not been established with respect to the claimed invention as the limitations of the claims are not taught or suggested by the cited combination of references and reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further submit that the combination of references do not render the claimed inventions obvious as Snyder *et al.* fails to teach or suggest that increased or abnormal human DAO activity is associated with the schizophrenia, depression, or bipolar disorder nor is there any teaching in the cited combination of references that decreased levels of D-serine are associated with schizophrenia, bipolar disorder, or depression. Applicants again respectfully submit that their disclosure has been taken as a blueprint for piecing together the prior art to defeat the patentability and that the combination of the cited prior art references, without any evidence that provides a suggestion, teaching, or motivation to combine these references, fails to raise a *prima facie* case of obviousness for the claimed invention.

With respect to the rejection of claims 30 and 32 are rejected under 35 U.S.C. § 103(a) as obvious Tsai *et al.* in view of Snyder *et al.* and Swiss-Prot Accession No. P14920 as applied to claims 20 and 21, and further in view of Ricci *et al.*, Applicants respectfully submit that the addition of the teachings of Ricci *et al.* fails remedy the deficiencies noted in the combination of Tsai *et al.* in view of Snyder *et al.* and Swiss-Prot Accession No. P14920. Thus, as a *prima facie* case of obviousness has not been established by the combination of references, the reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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